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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,293	08/23/2006	Yusuke Murata	03500.125697.	6810

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NEW YORK, NY 10104-3800

EXAMINER
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NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1795

MAIL DATE	DELIVERY MODE
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02/18/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,293	<b>Applicant(s)</b> MURATA, YUSUKE	
	<b>Examiner</b> ALEX NOGUEROLA	<b>Art Unit</b> 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/26/2008 and 11/06/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Blubaugh, Jr et al. US 5,964,993 (“Blubaugh”) as evidenced by Dillon US 4,945,125.

Addressing claim 1, Blubaugh discloses a structure having a plurality of mesopores (abstract and col. 05:59-64, which discloses pore sizes of about 0.01 to 0.1 micron (= 10 nm to 100 micron), which substantially overlaps the range 2 nm to 50 nm (the mesopore range) comprising:

a dendritic framework having mesopores passing through the framework in the direction intersecting the longitudinal direction of the framework (that the framework is dendritic is inherent as Blubaugh states, 'The term "semi-interpenetrating polymer network" is used herein to refer to membranes prepared by the methods described in either of the aforementioned patents to Dillon and their functional equivalents.' See col. 06:10-14. Dillon US 4,945,125 includes a scanning electron microphotograph showing the framework as dendritic. Indeed, Figure 2 in Blubaugh schematically shows a branch point (15) in the framework and refers to a network of nodes (col. 06:50-58), which implies a dendritic framework).

Addressing claim 2, for the additional limitation of this claim see Figures 2 and 3. One would infer that the pores will substantially be vertical if the membrane is horizontal as sample must percolate from the top of the sensor downwards toward the electrode.

Addressing claim 6, for the additional limitation of this claim see col. 06:52-58 and claim 1.

Addressing claim 8, for the additional limitation of this claim see the abstract and claim 22.

Art Unit: 1795

3. Claims 1, 2, and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Loureiro et al. US 2004/0122121 A1 ("Loureiro"). See paragraphs [0007], [0009], [0010], [0012], [0022], and [0054]-[0056]. As stated in the Written Opinion for International application no. PCT/JP2006/311469, "Loureiro discloses ... a structure having a dendritic framework comprising macropores and in the walls of the macropores mesopores. The mesopores are randomly distributed. Hence, some of them will be distributed perpendicular to a long direction of the structure. The structures can be used as a biomolecular sensor."

4. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lu et al. US 7,001,669 B2 ("Lu"). For claims 1-3 see the abstract; Figure 4 and col. 06:24-31. For claim 4 see col. 07:49 – col. 08:09.

5. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Iyer et al. US 6,958,480 B1 ("Iyer"). See the abstract; Figure 1; col. 03:25-30; col. 04:42-49; col. 05:64-65.

6. Claim 10 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Yoshioka et al. US 6,699,382 B2 ("Yoshioka"). See the abstract; Figures 1-9; col. 04:47 – col. 05:08; col. 06:22-57; col. 05:37-57; and claims 3 and 6.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer. Iyer discloses all of the initiations of underlying claim 1. See the abstract; Figure 1; and col. 03:25-30. Iyer does not specifically mention setting the pore size distribution so that 80% or pore of the mesopores fall within a range having a width of 10 nm and a maximal value; however, Iyer discloses that with his manufacturing method the pore sizes can be largely only one size, such as 4 nm or 8 nm, or a controlled range of sizes from 1 nm to 50 nm. See col. 03:26-30; col. 05:33-35; col. 07:57-60. Thus, to set the pore size within the claimed range is, barring a contrary, showing a mere change in size, so to speak, that one with ordinary skill in the art at the time of the invention could accomplish using the disclosure of Iyer.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer. Iyer discloses all of the initiations of underlying claim 1. See the abstract; Figure 1; and col. 03:25-30. Iyer does not specifically mention supporting a biological material in the mesopores; however, Iyer discloses and claims using the structure as a sample holder for desorption/ionization mass spectrometry. See col. 01:10-15 and claims 13 and 15. It would have been obvious to one with ordinary skill in the art at the time of the invention to use support biological material in the mesopores because as noted Iyer discloses and claims using the structure as a sample holder for desorption/ionization mass spectrometry and Iyer in discussing desorption/ionization mass spectrometry mentions that it is useful for studying biomolecules, such as proteins. See col. 01:52-58 and col. 02:63 – col. 03:03.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer. Iyer discloses all of the initiations of underlying claim 1. See the abstract; Figure 1; and col. 03:25-30. Claim 7 appears to be just requiring a plurality of structures within the scope of claim 1. If not already disclosed by Iyer, to provide a plurality of structures within the scope of claim 1 is either just mass manufacturing of the structures or just a matter of creating an assortment of structures with different pore sizes so that the

Art Unit: 1795

structure must appropriate or optimum for laser adsorption/ionization mass spectrometry of different samples of interest will be available.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blubaugh as evidenced by Dillon. Blubaugh discloses a sensor in which a biological material is supported in the mesopores of a structure according to claim 1. Blubaugh discloses a structure having a plurality of mesopores (abstract and col. 05:59-64, which discloses pore sizes of about 0.01 to 0.1 micron (= 10 nm to 100 micron), which substantially overlaps the range 2 nm to 50 nm (the mesopore range) comprising:

a dendritic framework having mesopores passing through the framework in the direction intersecting the longitudinal direction of the framework (that the framework is dendritic is inherent as Blubaugh states, 'The term "semi-interpenetrating polymer network" is used herein to refer to membranes prepared by the methods described in either of the aforementioned patents to Dillon and their functional equivalents.' See col. 06:10-14. Dillon US 4,945,125 includes a scanning electron microphotograph showing the framework as dendritic. Indeed, Figure 2 in Blubaugh schematically shows a branch point (15) in the framework and refers to a network of nodes (col. 06:50-58), which implies a dendritic framework). This structure is a component of an electrochemical glucose sensor located therein such that during operation body fluid containing glucose enters one surface of the structure and percolates therethrough the structure reacting with enzyme reagent in the pores so that glucose in the sample can

Art Unit: 1795

be accurately determined from current flow through an electrode on the opposing surface of the structure from through which the sample entered. See the abstract; claim 26; and col. 05:01-40. As such, the claimed “preparing”, “applying”, and “detecting” steps, if not implied are clearly obvious as they are the intended way in which the Blubaugh sensor is to be used.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Is claim 7 just requiring a plurality of the structures within the scope of claim 1?

***International Search Report for International Application No. PCT/JP2006/311469***

***(“Search Report”)***

Art Unit: 1795

15. The Search Report lists US 2004/122121 A1 as an "X" reference against claims 1, 2, 6-8. US 2004/122121 A1 has been used to reject claims 1, 2, and 608 under 35 U.S.C. 102(b) above.

16. The Search Report lists US 6696258 B1 as an "X" reference against claim 10. Claim 10 is directed to an enzyme electrode comprising a porous material that requires electron transfer substance immobilized on the porous material. US 6696258 B1, including the passages cited in the Search Report, does not mention an electrode or electron transfer substance. Yoshioka instead of US 6696258 B1 has been used to reject claim 10, under 35 U.S.C. 102(b), above.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1795

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/  
Primary Examiner, Art Unit 1795  
February 1, 2010